PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lotimil Plus 56.25 mg/2.11 mg chewable tablets (1.4–2.8 kg)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

56.25 mg lotilaner/2.11 mg milbemycin oxime

3. PACKAGE SIZE

1 tablet
3 tablets
6 tablets
18 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.
Administer with or after food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Local Representative:

MiPet
Owen Road
Diss
Norfolk
IP22 4ER

Tel: 01379 658042
products@cvsvets.com

14. MARKETING AUTHORISATION NUMBER

Vm 00879/5043

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lotimil Plus

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

56.25 mg lotilaner/2.11 mg milbemycin oxime

1.4–2.8 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp.: {mm/yyyy}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lotimil Plus 56.25 mg/2.11 mg chewable tablets for dogs (1.4–2.8 kg)
Lotimil Plus 112.5 mg/4.22 mg chewable tablets for dogs (> 2.8–5.5 kg)
Lotimil Plus 225 mg/8.44 mg chewable tablets for dogs (> 5.5–11 kg)
Lotimil Plus 450 mg/16.88 mg chewable tablets for dogs (> 11–22 kg)
Lotimil Plus 900 mg/33.75 mg chewable tablets for dogs (> 22–45 kg)

2. COMPOSITION

Each chewable tablet contains:

Active substances:

	Lotilaner	Milbemycin oxime
Dogs (1.4–2.8 kg)	56.25 mg	2.11 mg
Dogs (> 2.8–5.5 kg)	112.5 mg	4.22 mg
Dogs (> 5.5–11 kg)	225 mg	8.44 mg
Dogs (> 11–22 kg)	450 mg	16.88 mg
Dogs (> 22–45 kg)	900 mg	33.75 mg

White to beige round biconvex chewable tablet with brownish spots and bevelled edges with letter “I” debossed on one side of the tablet.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

For use in dogs with, or at risk from, mixed infestations/infections by ticks, fleas, mites, gastrointestinal nematodes, heartworm and/or lungworm. This veterinary medicinal product is only indicated for use when treatment against ticks/fleas/mites and gastrointestinal nematodes or the treatment against ticks/fleas/mites and prevention of heartworm disease/angiostrongylosis is indicated at the same time.

Ectoparasites

For the treatment of tick (*Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus* and *I. hexagonus*) and flea (*Ctenocephalides felis* and *C. canis*) infestations in dogs.

This veterinary medicinal product provides immediate and persistent killing activity for 1 month for ticks and fleas.

The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

For reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for one month. The effect is indirect due to the activity of the veterinary medicinal product against the vector.

For the treatment of demodicosis (caused by *Demodex canis*).

For the treatment of sarcoptic mange (*Sarcoptes scabiei* var. *canis*)

Gastrointestinal Nematodes

Treatment of gastrointestinal nematodes: hookworm (L4, immature adult (L5) and adult *Ancylostoma caninum*), roundworms (L4, immature adult (L5) and adult *Toxocara canis* and adult *Toxascaris leonina*) and whipworm (adult *Trichuris vulpis*).

Heartworm

Prevention of heartworm disease (*Dirofilaria immitis*).

Lungworm

Prevention of angiostrongylosis by reduction of the level of infection with immature adult (L5) and adult stages of *Angiostrongylus vasorum* (lungworm) with monthly administration.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances, or to any of the excipients.

6. SPECIAL WARNINGS

Special warnings:

The possibility that other animals in the same household can be a source of re-infection with ticks, fleas, mites, gastrointestinal nematodes, heartworm and/or lungworm should be considered, and these should be treated as necessary with an appropriate product.

The product should be used in dogs with, or at risk from, mixed infestations of ectoparasites (ticks, fleas or mites) and endoparasites (gastrointestinal nematodes and/or for prevention of heartworm/lungworm). In the absence of risk of co-infestation by external and internal parasites, a narrow spectrum product should be used. Ticks and fleas must attach to the host and commence feeding in order

to be exposed to the active substance; therefore the risk of the transmission of tick/flea- borne diseases cannot be excluded.

Specifically, as an acaricidal effect against *D. reticulatus* may take up to 48 hours, transmission of *B. canis canis* during the first 48 hours cannot be excluded.

For the treatment of infections with gastrointestinal nematodes the need for, and the frequency of, re-treatment as well as the choice of the treatment (monosubstance or combination product) should be evaluated by the prescribing veterinarian.

Maintenance of the efficacy of macrocyclic lactones is critical for *Dirofilaria immitis* prevention, therefore, to minimise the risk of resistance selection, it is recommended that dogs should be checked for both circulating antigens and blood microfilariae at the beginning of each heartworm season prior to starting monthly preventive treatments. The product is not effective against adult *D. immitis* and is not indicated for microfilariae clearance.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection/infestation based on its epidemiological features, for each individual animal.

Special precautions for safe use in the target species:

All safety and efficacy data have been acquired from dogs and puppies 8 weeks of age and older and 1.4 kg of bodyweight and greater. Use of this veterinary medicinal product in puppies younger than 8 weeks of age or less than 1.4 kg of bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.

The recommended dose should be strictly observed in MDR1 mutant ($^{-/-}$) dogs with a non-functional P-glycoprotein, which may include Collies and related breeds.

Prior to first administration, dogs in heartworm endemic areas or who have visited heartworm endemic areas must be tested for existing heartworm infection. At the discretion of the veterinarian, infected dogs should be treated with an adulticide to kill adult heartworms.

Administration of products containing milbemycin oxime (such as this product) to dogs with a high number of circulating microfilariae is not recommended in order to avoid hypersensitivity reactions associated with the release of proteins from dead or dying microfilariae.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental ingestion may cause gastrointestinal disturbances. In order to prevent access by children, keep the chewable tablets in the blister packs until required and keep the blister packs in the outer carton out of the reach of children.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after handling the tablets.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Laboratory studies in rats have not produced any evidence of teratogenic effects.

Fertility:

The safety of the veterinary medicinal product has not been established in breeding dogs.

Laboratory studies in rats have not produced any adverse effect on the reproductive capacity of males and females.

Interaction with other medicinal products and other forms of interaction:

Lotilaner and milbemycin oxime have been shown to be a substrate for P-glycoprotein (P-gp) and therefore could interact with other P-gp substrates (e.g. digoxin, doxorubicin) or other macrocyclic lactones. Therefore, concomitant treatment with other P-gp substrates could lead to enhanced toxicity.

Overdose:

No adverse reactions, other than those listed in section Adverse events, were observed in puppies (starting at 8 - 9 weeks of age) after administering up to 5 times the maximum recommended dose over 1 - 5 days (consecutive daily dosing) at monthly intervals on 9 occasions; or in adult dogs (starting at 11 months of age) after administering up to 5 times the maximum recommended dose over 1 - 5 days (consecutive daily dosing) at monthly intervals on 7 occasions; or in adult dogs (approximately 12 months old) after administration up to 6 times the maximum recommended dose as a bolus on a single occasion.

After administration of 5 times the maximum recommended dose to MDR1 mutant ($^{-/-}$) dogs with a non-functional P-glycoprotein, transient depression, ataxia, tremors, mydriasis and/or excessive salivation were observed.

7. ADVERSE EVENTS

Dogs.

Uncommon (1 to 10 animals / 1 000 animals treated):	Behavioural disorder[1,2] Diarrhoea[2], Vomiting[2] Muscle tremor[2] Pruritus (itching)[2] Anorexia (loss of appetite)[2], Lethargy[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Ataxia (incoordination)[3], Convulsion[3], Muscle tremor[3]

[1] Changes in behaviour.
[2] Generally self-limiting and of short duration.
[3] These signs typically resolve without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Oral use.

The veterinary medicinal product should be administered in accordance with the following table to ensure a dose of 20 to 41 mg lotilaner/kg bodyweight and 0.75 to 1.53 mg milbemycin oxime/kg bodyweight.

Dog bodyweight	Strength and number of Lotimil Plus chewable tablets to be administered				
	56.25 mg/ 2.11 mg	**112.5 mg/ 4.22 mg**	**225 mg/ 8.44 mg**	**450 mg/ 16.88 mg**	**900 mg/ 33.75 mg**
1.4–2.8 kg	1				
> 2.8–5.5 kg		1			
> 5.5–11 kg			1		
> 11–22 kg				1	
> 22–45 kg					1
> 45 kg	Appropriate combination of tablets				

Use an appropriate combination of available strengths to achieve the recommended dose of 20–41 mg lotilaner/kg and 0.75–1.53 mg milbemycin oxime/kg for animals > 45 kg bodyweight. Underdosing could result in ineffective use and may favour resistance development. To ensure a correct dosage, body weight should be determined as accurately as possible.

For infestations/infections with parasites, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle. If based on the veterinarian's opinion the dog requires re-administration(s) of the product, any subsequent administration(s) must follow the 1-month interval schedule.

Method of administration:

The veterinary medicinal product is a palatable chewable flavoured tablet. Administer the chewable tablet(s) with or after food.

9. ADVICE ON CORRECT ADMINISTRATION

Dogs living in non-heartworm endemic areas:

The veterinary medicinal product can be used as part of the seasonal treatment of ticks and/or fleas in dogs with diagnosed, or at risk from, concurrent gastrointestinal nematode infections or at risk of lungworm. A single treatment is effective for the treatment of gastrointestinal nematodes.

Dogs living in heartworm endemic areas:

Prior to treatment with the veterinary medicinal product the advice in section Special warnings should be considered.

For the prevention of heartworm disease and the concurrent treatment of tick and/or flea infestations, the veterinary medicinal product must be given at regular monthly intervals during the time of the year when mosquitoes, ticks and/or fleas

are present. The first dose of the veterinary medicinal product may be given after first possible exposure to mosquitoes, but not more than one month after this exposure.

When the veterinary medicinal product is used to replace another heartworm preventive product, the first dose of the product must be given within a month of the last dose of the former medication.

Dogs travelling to a heartworm region should start medication within a month after arrival there.

Heartworm prevention treatment should be continued monthly, with the last administration being given 1 month after the dog has left the region.

Lungworm:

In endemic areas, monthly administration of the veterinary medicinal product will reduce the level of infection with immature adults (L5) and adults of *Angiostrongylus vasorum* in the heart and lungs. It is recommended that lungworm prevention should be continued until at least 1 month after the last exposure to slugs and snails.

Seek veterinary advice regarding information on the optimal time to start treatment with this veterinary medicinal product.

For the treatment of demodicosis (caused by *Demodex canis*):

Monthly administration of the product for two consecutive months is efficacious and leads to a marked improvement of clinical signs. Treatment should be continued until two negative skin scrapings are obtained one month apart. Severe cases may require prolonged monthly treatments. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

For the treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*):
Monthly administration of the product for two consecutive months. Further monthly administration of the product may be required based on clinical assessment and skin scrapings.

10. WITHDRAWAL PERIODS

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Store in the original package

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Lotimil Plus chewable tablets	Vm Number
for dogs (1.4–2.8 kg)	00879/5043
for dogs (> 2.8–5.5 kg)	00879/5044
for dogs (> 5.5–11 kg)	00879/5045
for dogs (> 11–22 kg)	00879/5046
for dogs (> 22–45 kg)	00879/5047

Aluminium/aluminium blisters packaged into an outer cardboard box. Pack sizes of 1, 3, 6 or 18 tablets.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Local Representative and contact details to report suspected adverse reactions:

MiPet
Owen Road
Diss
Norfolk
IP22 4ER

Tel: 01379 658042
products@cvsvets.com

Manufacturer responsible for batch release:

Elanco France S.A.S., 26 Rue de la Chapelle, 68330 Huningue, France

17. OTHER INFORMATION

POM-V

Gavin Hall

Approved: 05 October 2026